

(a) The nystatin used in making the batch: 10 immediate containers of approximately 300 milligrams each.

(b) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend a representative number of tablets for 3 to 5 minutes in a high-speed glass blender with sufficient dimethylformamide to give a convenient concentration. Dilute an aliquot with sufficient dimethylformamide to give a stock solution containing 400 units of nystatin per milliliter (estimated). Further dilute the stock solution with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

(2) *Loss on drying*. Proceed as directed in § 436.200(b) of this chapter.

(3) *Disintegration time*. Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(1) of that section, except use distilled water in lieu of gastric fluid.

[39 FR 19134, May 30, 1974. Redesignated at 43 FR 43458, Sept. 26, 1978]

**§ 449.650b Nystatin vaginal suppositories.**

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity*. Nystatin vaginal suppositories contain in each suppository 100,000 units of nystatin in a suitable and harmless water soluble base. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of nystatin that it is represented to contain. Its moisture content is not more than 1.5 percent. The nystatin used conforms to the standards prescribed by § 449.50(a)(1).

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples*. In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The nystatin used in making the batch for potency, loss on drying, pH, and identity.

(b) The batch for potency and moisture.

(ii) Samples required:

(a) The nystatin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(b) The batch: A minimum of 30 suppositories.

(b) *Tests and methods of assay*—(1) *Potency*. Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of suppositories into a high-speed glass blender jar containing sufficient dimethylformamide to give a convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot with sufficient dimethylformamide to obtain a concentration of 400 units of nystatin per milliliter (estimated). Further dilute an aliquot with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

(2) *Moisture*. Proceed as directed in § 436.201 of this chapter.

[43 FR 43458, Sept. 26, 1978, as amended at 50 FR 19920, May 13, 1985]

**PART 450—ANTITUMOR ANTIBIOTIC DRUGS**

**Subpart A—Bulk Drugs**

Sec.

- 450.10a Sterile bleomycin sulfate.
- 450.20 Dactinomycin.
- 450.22 Daunorubicin hydrochloride.
- 450.24 Doxorubicin hydrochloride.
- 450.30 Idarubicin hydrochloride.
- 450.40 Plicamycin.
- 450.45 Mitomycin.

**Subpart B [Reserved]**

**Subpart C—Injectable Dosage Forms**

- 450.210 Sterile bleomycin sulfate.
- 450.220 Dactinomycin for injection.
- 450.222 Daunorubicin hydrochloride for injection.
- 450.224 Doxorubicin hydrochloride injectable dosage forms.
- 450.224a Doxorubicin hydrochloride for injection.
- 450.224b Doxorubicin hydrochloride injection.
- 450.230 Idarubicin hydrochloride for injection.
- 450.240 Plicamycin for injection.
- 450.245 Mitomycin for injection.